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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/369,016	08/05/99	FARMER S	GANEDEN-04(1

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EXAMINER	
NIKODEM,D	
ART UNIT	**PAPER NUMBER**
1633	6

DATE MAILED: 03/29/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/369,016	FARMER, SEAN	
	Examiner	Art Unit	
	David Nikodem	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☐ received.

2.☐ received in Application No. (Series Code / Serial Number) _____ .

3.☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

14) ☒ Notice of References Cited (PTO-892)
15) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
16) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6* .
17) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
18) ☐ Notice of Informal Patent Application (PTO-152)
19) ☐ Other: .

DETAILED ACTION

Priority

1. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78). The first line of the specification is required to make reference to the provisional application as follows: "This application claims the benefit of US Provisional Application No. 60/095,786, filed on 08/07/1998."

Claim Objections

2. Claim 41 is objected to because it depends on a non-existent claim, claim 48. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-44 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

5. Claims 1-44 are, in some mode or manner, drawn to "therapeutic compositions" or methods comprising a "therapeutically-effective concentration" of one or more non-pathogenic, lactic acid-producing bacterial species that possess the ability to increase the solubility and bioavailability of nutritional materials within the gastrointestinal (GI) tract.

6. As a first issue, the specification discloses a variety of bacterial strains and their concomitant function(s) and teaches formulations of vitamins/minerals to be used for delivery in combination with said bacterial strain(s). However, the specification does not teach what therapy the therapeutic compositions and the methods comprising therapeutically effective concentrations would be treating. The language "therapeutic" directly implies that a therapy is being given. It is unclear as to what is the therapy that these compositions are addressing.

7. As a second issue, the delivery of bacteria and probiotic organisms in general is considered unpredictable. Ziemer, *et al.* teaches that for effective oral delivery of probiotic microorganisms, the bacteria must first survive the conditions of the stomach and small intestine before reaching colon of the large intestine, where a probiotic effect can potentially be seen. Furthermore, the reference demonstrates (see p. 475) that a major problem using probiotic strains of bacteria is "the inability of the fed organism to colonise the colon and become part of the microbial community." The feasible delivery of each strain must b determined on a case to case basis. It would requir undue trial and error experimentation for one skilled in the art to determine whether or not a

specific strain of non-pathogenic, lactic acid producing bacteria could be successfully delivered, *in vivo*.

8. As a third issue, the specification does not teach that the disclosed formulation(s) will provide a therapeutic effect, *in vivo*. It is unclear that the administration of the therapeutic composition of bacteria and vitamins and/or minerals will increase the solubility and bioavailability of nutritional materials within the GI tract. Salminen, *et al.* teaches (see p. S152) that "the colonic microflora is a complex interactive community of organisms and its functions are a consequence of the combined activities of the microbial components" and thus, "[d]isturbances of the intestinal microflora may lead to other disturbances and dysfunctions of the gut." Introduction of foreign bacteria and vitamins/minerals may disturb the microflora in a manner such as to not see an effect by the delivered composition.

9. Furthermore, bacteria are involved in a variety of processes in the colon and "[b]acterial counts of individual species range over several orders of magnitude, and the nutrition and metabolic products of different bacterial groups vary considerably" (Salminen, *et al.*). The aforementioned facts suggest that the fate of the delivered vitamins/minerals in terms of solubility and availability would rely, at least in part, on the bacterial strain(s) utilized in the therapeutic composition, as well as the preexisting microflora of the animal accepting the therapeutic composition. The specification gives no guidance as to what th rapeutic strains are suitable for which organisms and no examples of any success seen upon delivery of said therapeutic composition.

Therefore, it would require undue experimentation to determine, the strain(s) of bacteria needed for each species of animal and for each composition of vitamins/minerals to elicit a therapeutic effect.

10. As a fourth issue, the specification provides no guidance to one skilled in the art in the selection of which bacteria for 1) therapeutic treatment of which ailment and 2) increasing the solubility and bioavailability of which nutrient(s). The specification discloses a variety of species and strains of bacteria and varying therapeutic compositions, including multiple vitamins and minerals. However, the specification does not teach which therapeutic compositions of which species of bacteria and in which formulation with certain vitamins and minerals should be used for the treatment of which ailment(s). It would require undue experimentation for one skilled in the art to determine which therapeutic composition is to be used for which specific ailment.

11. In light of the aforementioned issues, the invention is not enabled.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1-44 are rejected over the breadth of the claims under 35 U.S.C. 102(b) as being anticipated by Fuller.

14. The claimed invention is drawn to therapeutic compositions and therapeutically effective concentrations of nonpathogenic, lactic acid producing bacteria which posses the ability to increase the solubility and bioavailability of nutritional materials within the GI tract of an animal.

15. Fuller (page 7) discloses that benefit[s] from "probiotic supplementation are numerous and include improved utilization of food [that] may be achieved by increased efficiency of existing digestive processes or by promoting the digestion of previously indigestible substances."

16. Claims 1-44 are rejected over the breadth of the claims under 35 U.S.C. 102(b) as being anticipated by Friend.

17. Friend (page 126) discloses that "Lactobacilli have been shown to constitute one of the major groups of intestinal and fecal organisms in animals and humans and recent scientific evidence attests their importance in human nutrition and health." Furthermore, "a number of studies have established that fermentation by the lactobacilli improves the nutritional value of food products by increasing the quantity as well as the availability, digestibility and assimilability of nutrients."

18. The references provide evidence for a variety of therapeutic effects seen by lactobacilli and other organisms. This evidence directly anticipates the claimed invention of a therapeutic composition using non-pathogenic, lactic acid-producing bacteria since the references provide evidence for a therapeutic effect by lactobacilli

and other lactic-acid producing bacteria. In view of such, either Fuller or Friend anticipate the claimed invention.

19. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Nikodem whose telephone number is (703) 308-8361. The examiner can normally be reached on M-F, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3230 for regular communications and (703) 305-3230 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1123.

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March 27, 2000

JOHN L. LeGUYADER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600